Science For A Better Life

Clinical Study Synopsis

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Date of study report:	16 Oct 2014
Study title:	A Study to Assess the Stinging Potential of Products in Human Eyes
Sponsor's study number:	17913
NCT number:	NCT02872194
EudraCT number:	Not applicable
Sponsor:	Bayer
Clinical phase:	Not applicable
Study objectives:	• The primary objective of this study was to evaluate the human eye stinging potential of test sun care product(s). • The secondary objective of this study was to evaluate the safety of the sun care product(s) by monitoring adverse events (AEs) throughout the study.
Test drug:	BAY 112233, SPF 50, *Y55-170, X72-151, Y49-034*
Name of active ingredient(s):	BAY 112233
Dose:	Control: 10 µL in one eye Product: 10 uL in other eye
Route of administration:	Eye installation
Duration of treatment:	Single-dose administration for 1 hr
Reference drug:	Shampoo control (*X46-046 J&J Baby Shampoo*, 10% in tap water)
Dose	10 µL
Route of administration	Eye installation
Duration of treatment	Single-dose administration for 1 hr
Indication:	Sunscreen agents
Diagnosis and main criteria for inclusion:	• Male or female subjects, aged 18 to 65 years • No medical conditions of the eyes as determined by the subjects' medical history and confirmed by ophthalmologist • Subjects do not wear contact lenses or, if he/she does wear contact lenses, is willing to refrain from wearing these during the day of and day after the study • Subject is willing to have the test materials instilled into the eyes and follow all protocol requirements

	• Subject is willing to refrain from using false eyelashes of any type or any topical prescription, OTC or cosmetic products on their eyes, eyelids, eyelashes or the peri-orbital areas of the face on the day of the study. Subjects should refrain from use of make-up on testing day
Study design:	The study was a single blind study with randomized application of control and test product into one of the subjects two eyes.
Methodology:	Using the thumb and forefinger of one hand, a trained technician gently retracted the lower eyelid from the eyes of the subject forming sacs in the conjunctival tissue, and placed 10 µL of the appropriate test or control article into the lower conjunctival sac of the eye. Immediately after the materials had been instilled, the subject was instructed to close his/her eyelids and move the eyes up and down and from side to side to distribute the instillates over the orbit surface. The subject was asked if he/she felt any discomfort and, if so, he/she was asked to describe the character and intensity of the discomfort perceived in each eye. Information was solicited from the subject throughout the one minute period. At the end of 1 minute, the subject was instructed to open his/her eyes and move them from side to side and up and down. Using a slit-lamp, the degree of inflammation was recorded. The subject was asked if any discomfort was present, and if so, to describe its character and intensity in each eye. At 2 minutes after installation, the eyes were again examined using the slit-lamp and the degrees of inflammatory changes, if any, were graded and the scores were recorded and the eyes were washed out with water. The subject was to wash their eyes 6 times, or until they felt the product was removed completely. The subjects were then asked which of the two products was the milder, the one in the right eye or the one in the left eye. The preference or lack thereof was recorded. Follow-up examinations are done 15, 60 minutes and 24 hours after instillation. Safety and tolerability of the study drugs were monitored throughout the study with scores of 4 in any of the assessed category being considered an adverse event.
Study center(s):	The study was conducted at a single center in the United States.
Publication(s) based on the study (references):	None at the time of report creation.

Study period:	Study Start Date: 05 SEP 2014 Study Completion Date: 06 SEP 2014
Early termination:	Not applicable
Number of subjects:	Planned: Minimum of 5 subjects to complete the test of each test product. Randomized The two eyes per subject were randomized for either installation of control or test product. Analyzed: 21 subjects completed to test Y55-170, X72-151, or Y49-034
Criteria for evaluation	
	Safety: Subjective discomfort in the eye was assessed based on questions by an Ophthalmologist to the subject, and a 5-category intensity scale. Tearing/Lacrimation and objective inflammation was assessed by the Ophthalmologist using a 5-category assessment score for each of the categories. Post installation eye effects (pain/stinging, itching, dryness, scratchiness, discomfort preventing sleep, discomfort upon awakening, excessive discharge upon awakening, pain in bright sunlight) at 24 hours were assessed using a 5-category intensity score.
Statistical methods:	Number and percentage of subjects will are summarized by treatment for different grading scales.
Substantial protocol changes:	Protocol amendment 1introduced the following changes: • Changed the test article dose from 5 µl to 10 µl per drop • Changed the wording for the dilution of the J&J Baby Shampoo • Changed the page numbers

Subject disposition and baseline

In total 21 completed this study of which 7 completed the study for Y55-170, 7 completed the study for Y72-151 and 7 completed the study for Y49-034

Safety evaluation

Y55-170

Subjective assessment of discomfort

Subjects reported faint to mild discomfort up to 60 seconds post instillation and during the slit lamp more frequently for the product than the control. There were no instance of eye effects reported by subjects 24 hours post-instillation for both the product and the control.

Objective Ophthalmologist assessment

There were no notable differences between the product and the control in objective assessment of tearing/lacrimation and conjunctival inflammation of the cornea and iris. Instances of Grade 2 (+diffused faint redness) for conjunctival inflammation of the palpebra and sclera were more frequent for the sample than the control 1- and 2-minute post application based on the slit lamp examinations.

X72-151

Subjective assessment of discomfort

Subjects reported faint, mild and moderate discomfort up to 60 seconds post instillation and during the slit lamp assessments more frequently for the product than the study control. At 24 hours post-instillation, one subject reported pain/stinging and one subject reported excessive discharge upon waking for the product compared to no instances of eye effects reported by subjects for the study control.

Objective Ophthalmologist assessment

Instances of Grade 2 (Meager tear flow) and Grade 3 (Moderate tear flow) for tearing/lacrimation and instances of Grade 2 (+diffused faint redness) for the conjunctival inflammation of the palpebra and sclera were more frequent for the product and the control 1- and 2-minutes post application based on the slit lamp examinations. There were no notable differences in the objective assessments of conjunctival inflammation for the cornea and iris.

Y49-034

Subjective assessment of discomfort

Subjects reported faint, mild and in one instance moderate discomfort up during/following the slit lamp assessments more frequently for the product than the study control. At 24 hours post-instillation, one subject reported pain/stinging and one subject reported dryness for the sample compared to no instances of eye effects reported by the subjects for the study control.

Objective Ophthalmologist assessment

Instances of Grade 2 (Meager tear flow) and in one instance a Grade 3 (Moderate tear flow) for tearing/lacrimation were more frequent for the product and the study control approximately 50 seconds post-installation and during 2-minute slid lamp assessment. Instance of Grade 1 (increased capillary show) and Grade 2 (+diffused faint redness) were also more frequent for the sample than the study control during the 2 minute slit lamp assessment. There were no notable differences between the

sample the study control in the objective assessments of conjunctival inflammation of the cornea, iris and palpebra.

Overall conclusions

All three test products produced higher subjective discomfort scores as rated by subjects and objective irritation scores as graded by the ophthalmologist in comparison to the study control.